**UNITED STATES DISTRICT COURT**
**SOUTHERN DISTRICT OF WEST VIRGINIA**
**AT CHARLESTON**

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| **IN RE: ETHICON, INC. PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION** | **Master File No. 2:12-MD-02327**<br>**MDL No. 2327** |
| **THIS DOCUMENT RELATES TO:**<br><br>**WAVE 1 CASES** | **JOSEPH R. GOODWIN**<br>**U.S. DISTRICT JUDGE** |

**REPLY IN SUPPORT OF MOTION TO EXCLUDE CERTAIN OPINIONS OF ABBAS SHOBEIRI, M.D.**

Plaintiffs' brief does not seriously refute the well-settled legal principles cited in Ethicon's brief as a basis to exclude Dr. Shobeiri's testimony. Defendants have moved the Court to preclude Dr. Shobeiri from testifying regarding

- Alleged design defects in the TVT-O and Prolift that are not supported by reliable scientific evidence and that he is not qualified to address.
- "Safer" alternative products whose comparative safety and efficacy have not been quantified.
- Alleged inadequate warnings that he is not qualified to address.
- Alleged inadequate training and education that is not relevant.
- Defendants' knowledge, state of mind or intent.

Nevertheless, to respond to certain arguments advanced by Plaintiffs, Defendants Ethicon, Inc. and Johnson & Johnson (hereinafter "Defendants") submit this reply in support of their motion to exclude certain opinions of Dr. Shobeiri.

## I. Dr. Shobeiri is Not Qualified to Render Opinions on Design Defect and Product Warnings.

Defendants have moved to exclude Dr. Shobeiri's opinions that TVT-O and Prolift are defectively designed. (Mem. In Supp. of Mot. to Exclude ("Mem. In Supp.") at 3-5 (D.E. 2077)). Plaintiffs claim that Dr. Shobeiri has advanced a whole host of design-defect opinions in his report, nearly all of which he failed to explain at his deposition. (Resp. in Opp'n, ("Resp.") at 3-4 (D.E. 2170)). When questioned at his deposition as to the *specific* aspect of these products' design that Dr. Shobeiri contends is defective, Dr. Shobeiri identified *only* "the fact that [it] coils . . .[,] ropes . . .[,] doesn't stay flat . . .[, and] has edges that fray." (Mem. In Supp. at 3). He identified *only* "those [as] the design flaws." *Id.* The Court should limit Dr. Shobeiri's design-defect testimony at trial, if any, to only those specific defects delineated by him at his deposition.

Regardless of the shifting nature of Dr. Shobeiri's opinions on design defect, it is clear that Dr. Shobeiri is unqualified to render opinions on design defect and warnings such as the Instructions for Use (IFUs) included in the TVT-O and Prolift devices. He has no expertise in these areas and testified to that effect in deposition. It is well established that an expert's impressive credentials in discrete areas do not qualify such experts to testify in every related field. Instead, the expert's qualifications must have a sufficient connection with the specific subjects at issue in the case. *See, e.g., Free v. Bondo-Mar-Hyde Corp.*, 25 F. App'x 170, 172 (4th Cir. 2002) (affirming the exclusion of testimony because highly credentialed expert nevertheless lacked knowledge of specific matters essential to subject of his opinion).

Plaintiffs admit that Dr. Shobeiri is not a biomaterials engineer, but claim that his "involve[ment] with the design of a polypropylene mesh product for submission to the FDA," as well as his general experience implanting approximately 50 TVT-O devices, qualify him to render design defect opinions. (Resp. at 6-7). For that product, a fecal incontinence product, Dr.

Shobeiri's role was limited to studying the anatomical course of the product—not its design. (*See* Exhibit 3 to Resp. at 35:11-15). This is a far cry from actual experience with the design of a relevant product. This Court has previously precluded a urogynecologist from testifying about product design where the urogynecologist lacked experience with the actual design of the product. *See Tyree v. Bos. Sci. Corp.*, 54 F. Supp. 3d 501, 581 (S.D. W. Va. 2014). It should do the same in this case.

Furthermore, with respect to warnings, although Dr. Shobeiri testified at his deposition that he was involved in the FDA approval process for a different product called Topas, he also testified that he has never written or been involved in writing any IFUs. Specifically, Dr. Shobeiri testified to the following:

> Q: Have you ever written a warning for any product
> MS. THOMPSON: Object to form
> A: Have I ever written a warning for any products? No.
> Q: Have you ever had any special education about warnings and how they should be written?
> Ms. THOMPSON: Object to form.
> A: Well, I have read a lot of IFUs and in medical school we, you know, we learn about these things.
> Q: Well, other than your medical school training and reading IFUs, have you had any specialized training in the preparation or dissemination of warnings?
> A: Could you expand on that?
> Q: Not really.
> A: Uh-huh.
> Q: You want to ask it read the question again
> Ms. THOMPSON: Object to form.
> A: So like have I gone to law school?
> Q: I know you haven't been to law school because I've read your resume.
> A: Uh-huh.
> Q: My question stands as asked. Can you answer it?
> A: Beside the training I have had I have not had any other training.
> Q: So confined to what you leaned in medical school and in reading IFUs?
> MS. THOMPSON: Object to form.

A: Yes, I'm not a lawyer.

*See* Exhibit E to Defendants' Motion to Exclude, February 27, 2016 Dep. of Abbas Shobeiri, M.D. at 36:7-38:11. Here, it is clear that Dr. Shobeiri cannot possibly be qualified to render opinions about the adequacy of the IFU in the instant matter. The only "training" on IFUs he has received occurred in medical school, arguably something every doctor would have also received. Certainly the training received in medical school alone cannot qualify anyone, including Dr. Shobeiri, to now be an expert in the adequacy of an IFU.

The deficiencies in Dr. Shobeiri's ability to opine in the instant matter are analogous to the Court's preclusion of the opinions of Dr. Bob Shull, plaintiff's urogyncology expert, in the *C.R. Bard* MDL. *In re: C.R. Bard, Inc.*, 948 F. Supp. 2d 589, 611 (S.D. W. Va. 2013), the Court precluded Dr. Shull, from testifying about product warnings when it determined that Dr. Shull offered conclusory opinions about the defendant's product warnings, and failed to "provide a reliable basis for his opinions of what Bard should have done with respect to its opinions." *Id.* According to the Court, "[t]his is likely the result of Dr. Shull's lack of expertise in the specific area of warnings and labels for medical devices…" *Id.* Similarly, like Dr. Shobeiri in the instant matter, Dr. Shull testified at his deposition that he had never developed a product warning. *Id.* Accordingly, the Court concluded that "[d]espite his stellar qualifications as a urogynecologist, Dr. Shull is unqualified to testify on the specific issue of product warnings, as evidence by his lack of familiarity with the process." *Id.* The result should be the same in the instant matter. Despite Dr. Shobeiri's qualifications as a pelvic surgeon and an OBGYN, these medical qualifications do not qualify him to become an expert in product warnings and as a result these opinions should be barred.

As to Plaintiffs' claims that Dr. Shobeiri has implanted approximately 50 TVT-O products (Resp. at 7, 8), this response essentially boils down to the contention that Dr. Shobeiri is an established urogynecologist with years of experience; therefore, the Court should find him qualified to testify as to biomaterial properties of mesh and/or warnings. This type of argument has failed to persuade this Court on previous occasions, *see, e.g.*, *Ramsey*, 2016 WL 2622006, at *5 ("The plaintiff fails to provide any argument addressing how Dr. Margolis is an expert on any of the above subject matters, beyond the basic assertion that Dr. Margolis is an established urogynecologist with years of experience with pelvic mesh products."), and it is no more persuasive now.[1] Here, like in the *C. R. Bard*, MDL, the Court should preclude Dr. Shobeiri from testifying about product warnings and design defects. These subjects are outside his area of expertise.

## II. Dr. Shobeiri's Opinions That There Were Safer Alternative Procedures is Not Relevant.

Defendants have moved to exclude Dr. Shobeiri's opinions that there were other equally or more-effective alternative procedures to treat the conditions that TVT-O and Prolift were designed to treat, including abdominal or laparoscopic sacrocolpopexy. (Mem. In Supp. at 5-7). With respect to alternative procedures such as mesh implanted through abdominal or laparoscopic sacrocolpopexy, Defendants contended that these are not alternative *designs* or alternative *products*. *See Schmidt v. C.R. Bard, Inc.*, 2013 WL 3802804, at *2 (D. Nev. July 22, 2013) ("[N]on-mesh repair is not an alternative design and does not meet Plaintiff's burden to

[1] Plaintiffs also fail to respond to Defendants' arguments that the sweeping statements in Dr. Shobeiri's reports, such as the statements that vaginal pain following a mesh procedure is categorically "more likely than not" caused by mesh," (*see* Mem. In Supp. at 4), and these opinions should be excluded for failure to identify any study supporting them. *See, e.g.*, *Ramsey v. Bos. Sci. Corp.*, 2016 WL 2622006, at *4 (S.D. W.Va. May 5, 2016) ("The plaintiff does not address the majority of BSC's arguments on this point, and I decline to raise counterarguments for the plaintiff when she has failed to address BSC's arguments in her briefing.").

support" a design-defect claim"). In response, in an effort to save Dr. Shobeiri's alternative-procedure testimony, Plaintiffs rely on the red-herring argument that this Court has previously concluded that "mesh constructed from native tissues" could serve as evidence of an alternative design. (Resp. at 9). This argument fails to persuade. Even if this Court has held that "mesh constructed from native tissues" could serve as evidence of an alternative *design*, this is not the same thing as an alternative *procedure*, which is what Dr. Shobeiri opines on. Dr. Shobeiri's opinions regarding alternative procedures are not relevant to this case and violate Federal Rule of Evidence 702, which requires that an expert's opinion be specifically applied "to the facts of the case." Because Dr. Shobeiri's opinion about these supposed safer procedures will not help the trier of fact "to determine a fact in issue," it should be excluded. *See Lewis v. Ethicon, Inc.*, No. 2:12-cv-4301, 2014 WL 186872, at *6 (S.D. W. Va. Jan. 15, 2014).

## III. Dr. Shobeiri's Opinions Regarding The Adequacy Of The TVT-O And Prolift IFUs Lack a Reliable Basis.

In addition to the fact that he is not qualified to opine on FDA regulatory processes for approving warnings, Dr. Shobeiri should also be prohibited from testifying regarding the adequacy of the IFUs. Defendants moved to exclude Dr. Shobeiri's opinions that the TVT-O and Prolift IFUs are inadequate because they supposedly do not go into great detail about the frequency and permanence of the alleged risks. (Mem. In Supp. at 9). Dr. Shobeiri has never disputed that the TVT-O IFU warns of extrusion, erosion, inflammation, infection, and urinary tract obstruction, and the Prolift IFU warns of inflammation, erosion, extrusion, and other risks. (*Id.*) He simply takes issue with the fact that Ethicon did not use the "magic words" of Plaintiffs' preferred litigation theories in its warnings. Crucially, Dr. Shobeiri cites no literature regarding warnings in support of his opinions, referring only to a "general body of medical literature that he has read, reviewed, and considered throughout his years of practice." (Resp. at

13). Such generalized "support" for his opinions cannot and does not constitute reliable methodology. His opinions should be excluded. *See Cisson v. C.R. Bard, Inc.*, 948 F. Supp. 2d 589, 606 (S.D. W. Va. 2013) (excluding expert opinions based only on clinical experience without any "basis in reliable methodology").

## IV. Dr. Shobeiri's Opinions Regarding Inadequate Education Or Training Are Not Relevant And His Inconsistent Testimony Underscores His Unreliable Methodology.

Dr. Shobeiri opines that "community doctors" are uninformed about complications of mesh and that Defendants' training program was inadequate. (Mem. In Supp. at 10). Inadequate training is not relevant because he does not ascribe to Defendants any duty to train. Without that opinion, his opinions regarding training are not relevant to this case and violate Federal Rule of Evidence 702, which requires that an expert's opinion be specifically applied "to the facts of the case." Because Dr. Shobeiri's opinions about training will not help the trier of fact "to determine a fact in issue," it should be excluded. *See Lewis v. Ethicon, Inc.*, No. 2:12-cv-4301, 2014 WL 186872, at *6 (S.D. W. Va. Jan. 15, 2014). Moreover, Plaintiffs cite no law for the proposition that "once Defendants had undertaken the responsibility of education/training, [they] were obligated to provide adequate education/training to the physicians." (Resp. at 15). Not only is there no law cited for this proposition, there is no citation showing that this is Dr. Shobeiri's opinion. Dr. Shobeiri has not expressed any opinion on Defendant's "duty" or "obligation" to train. (Mem. In Supp. at 10).

Furthermore, Plaintiffs fail to rebut the conclusion that Dr. Shobeiri offered inconsistent testimony at his deposition. Dr. Shobeiri first testified that he would expect physicians in the community to read IFUs and be aware of medical literature warning about various complications of mesh, including contraction. He also (inconsistently) testified that physicians were uninformed about the complications of mesh. (Mem. In Supp. at 11). Plaintiffs confusingly

state that "information [was] available in the medical community, [but] the medical community was not aware of the complications associated with pelvic mesh products." (Resp. at 16). Given Dr. Shobeiri's opinion that he expects doctors to be aware of literature available to the medical community before implanting a product, it is hard to see how else information could have been provided to physicians before they could become sufficiently "aware of complications" with mesh. These inconsistencies further underscore the unreliability of Dr. Shobeiri's methodology. *See Sanchez v. Bos. Sci. Corp.*, No. 2:12–cv–05762, 2014 WL 4851989, at *14 (S.D. W. Va. Sept. 29, 2014) (excluding opinion where "Dr. Margolis's inconsistencies [in contradicting himself in his deposition] seem to directly shed light on the unreliability of his method").

## V. The Court Should Exclude Dr. Shobeiri's Opinions About Ethicon's Knowledge, State Of Mind, Or Bad Acts.

Plaintiffs appear to argue that Dr. Shobeiri is not offering "impermissible 'state of mind,' 'intent,' or 'bad acts' opinions." (Resp. at 17). They characterize his opinions on Ethicon's state of mind merely as "a review of internal corporate documents . . . for the purpose of explaining the basis for his or her opinions." (*Id.*) Yet Dr. Shobeiri seeks to offer opinions that "Ethicon knew that the TVT-O was associated with more pain than other slings;" that Ethicon "did not consider physician training to be a priority, or even a necessity;" and that "Ethicon[] [knew] about the risks inherent in the design of its products which Ethicon's internal documents specifically recognize." (Mem. In Supp. at 12). These are unquestionably impermissible opinions as to state of mind. This Court has consistently found that experts in this MDL may not testify about device manufacturers' "knowledge, state of mind, alleged bad acts, failures to act, and corporate conduct and ethics." *Cisson*, 948 F. Supp. 2d at 611; *Huskey*, 29 F. Supp. 3d at 703. Dr. Shobeiri's opions should be excluded in this case.

## CONCLUSION

For the reasons set forth above, the Court should limit the parameters of Dr. Shobeiri's testimony consistent with the foregoing.

Respectfully submitted,

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**CERTIFICATE OF SERVICE**

I certify that on May 16, 2016, I electronically filed this document with the Clerk of the Court using the CM/ECF system which will send notification of this filing to CM/ECF participants registered to receive service in this MDL.

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